

REMARKS

Claims 1-3, 5-21, and 23-36 are pending. Claims 13-14 and 31-32 are withdrawn.

Claims 4 and 22 were previously canceled.

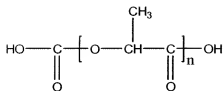
Rejections under 35 USC § 112

Claims 15 and 33 are rejected under 35 U.S.C. 112, first paragraph, as allegedly lacking sufficient description with respect to the definition of m and n as defined by claims 15 and 33. Applicants respectfully direct the Examiner to page 6, lines 13-18, which specifically states that m can be ≥ 2 , and n can be ≥ 2 . The rejections of claims 15 and 33 as lacking sufficient description of “m” and “n” are therefore erroneous.

Rejections under 35 USC § 102

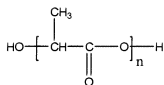
Claims 1-3, 5-12 and 15-18 are rejected under 35 U.S.C. 102 (b) as being anticipated by Yang et al. (US 6,258,121 B1).

Claim 1 defines a medical article comprising an implantable substrate having a coating. The coating includes a polymer comprising a derivative of carboxylated or hydrolyzed poly(lactic acid), or a block-copolymer having at least one moiety comprising a derivative of carboxylated or hydrolyzed poly(lactic acid). The hydrolyzed poly(lactic acid) has an average molecular weight between about 1,000 and about 20,000 Daltons. The polymer comprising a derivative of hydrolyzed poly(lactic acid) has two terminal hydroxyl groups. The block-copolymer having at least one moiety comprising a derivative of hydrolyzed poly(lactic acid) has two terminal hydroxyl groups. Note, a carboxylated poly(lactic acid) has a structure of:



. As described at page 11, lines 18-21, a coating having a polymer comprising carboxylated poly(lactic acid) or a mixture of a hydrolyzed poly(lactic acid) and un-hydrolyzed poly(lactic acid) can accelerate the degradation rate of the coating, which, as described at page 3, lines 12-14, can be very desirable.

Yang describes a coating that can include a poly(lactic acid)-co-poly(ethylene oxide) (PLA-PEO) co-polymer. Yang fails to teach a coating having a polymer as defined by claim 1. Contrary to the Examiner's assertion, PLA-PEO would not necessarily have two terminal hydroxyl groups. Further, hydrolysis of PLA-PEO would result in a mixture of poly(ethylene oxide) having one or two hydroxyl groups, depending on the process forming PLA-PEO described therein, and monomeric PLA, or oligomers or polymers of PLA, which have a general formula of



. It is therefore clear that hydrolysis of PLA-PEO as described in Yang would not form a polymer or copolymer as defined in claim 1. Therefore, Yang does not describe a medical device having a coating as defined by claim 1. Accordingly, claim 1 is patentably allowable over Yang under 35 U.S.C. §102(b). Claims 2, 3, 5-12, and 15-18 depend from claim 1 and are patentably allowable over Yang under 35 U.S.C. §102(b) for at least the same reason.

Rejections under 35 USC § 103

Claims 1-3, 5-12, 15-21, 23-30 and 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yang (US 6,258,121B1) in view of Okada (US 6,113,943).

As discussed above, claim 1 describes a medical device having a coating including a polymer comprising a derivative of carboxylated or hydrolyzed poly(lactic acid), or a block-copolymer having at least one moiety comprising a derivative of carboxylated or hydrolyzed poly(lactic acid). The hydrolyzed poly(lactic acid) has an average molecular weight between about 1,000 and about 20,000 Daltons. The polymer comprising a derivative of hydrolyzed poly(lactic acid) has two terminal hydroxyl groups. The block-copolymer having at least one moiety comprising a derivative of hydrolyzed poly(lactic acid) has two terminal hydroxyl groups. **To the extent Yang is relevant, Yang does not describe or teach (1) a polymer comprising a derivative of hydrolyzed poly(lactic acid) has two terminal hydroxyl groups or (2) a block-copolymer having at least one moiety comprising a derivative of hydrolyzed poly(lactic acid) has two terminal hydroxyl groups.**

Okada describes a sustained-release preparation of hydrolyzed polymer of lactic acid having average molecular weight of 25,000 to 60,000 Daltons for releasing physiologically active substance. As discussed above, a hydrolyzed polymer of lactic acid would have a general

formula of
$$\text{HO}-\left[\text{CH} \begin{array}{c} | \\ \text{CH}_3 \end{array} - \text{C} \begin{array}{c} \parallel \\ \text{O} \end{array} - \text{O} \right]_n - \text{H}$$
. This polymer is clearly different from the one defined by claim 1, **which can include a polymer comprising a derivative of hydrolyzed poly(lactic acid) has two terminal hydroxyl groups or (2) a block-copolymer having at least one moiety comprising a derivative of hydrolyzed poly(lactic acid) has two terminal hydroxyl groups.** Accordingly, Yang and Okada in combination do not teach a medical device having a coating as defined by claim 1. Claim 1 is therefore patentably allowable over Yang in view of Okada under 35 U.S.C. 103(a). Claims 2, 3, 5-12, and 15-18 depend from claim 1 and are patentably allowable over Yang in view of Okada under 35 U.S.C. §103(a) for at least the same reason.

Claim 19 defines a method for fabricating a medical article having a coating. The coating includes a polymer or a copolymer similar to the polymer or copolymer as defined by claim 1. As seen from the discussion of claim 1, Yang and Okada together do not teach this polymer or copolymer. Accordingly, claim 19 is patentably allowable over Yang in view Okada under 35 U.S.C. §103(a). Claims 20, 21, 23-30, and 33-36 depend from claim 19 and are patentably allowable over Yang in view of Okada under 35 U.S.C. §103(a) for at least the same reason.

Double Patenting

Claims 1-9, 11, 15, 18, 19-21, 23-27, 29 and 36 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent 7,169,404. Applicants believe the terminal disclaimer over U.S. Patent 7,169,404 submitted herewith renders the rejection moot.

The undersigned authorizes the examiner to charge any fees that may be required or credit of any overpayment to be made to Deposit Account No. 07-1850.

CONCLUSION

Withdrawal of the rejection and allowance of the claims are respectfully requested. **If the Examiner has any suggestions or amendments to the claims to place the claims in condition for allowance, applicant would prefer a telephone call to the undersigned attorney for approval of an Examiner's amendment.** If the Examiner has any questions or concerns, the

Examiner is invited to telephone the undersigned attorney at (415) 393-9885.

Date: September 18, 2007
Squire, Sanders & Dempsey L.L.P.
One Maritime Plaza, Suite 300
San Francisco, CA 94111
Telephone (415) 393-9885
Facsimile (415) 393-9887

Respectfully submitted,



Zhaoyang Li, Ph.D., Esq.
Reg. No. 46,872